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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/005,318	01/09/1998	MICH B. HEIN	310098401C1	2353

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/005,318	Applicant(s) HEIN ET AL.	
	Examiner David S. Romeo	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42,52,54-60,62-65,67-69,73 and 76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42,52,54-60,62-65,67-69,73 and 76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 42,52,54-60,62-65,67-69,73 and 76 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20060427</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/01/2006 has been entered.

Claims 42, 52, 54–60, 62–65, 67–69, 73, and 76 are pending.

Applicants' election of the species of targeting molecule comprising a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 covalently linked via a peptide bond to an antigen combining site is acknowledged. Claims 44, 46-49, 51, 53, 66, 75, 78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 12/18/2002.

Maintained Formal Matters, Objections, and/or Rejections:***Double Patenting***

Claims 42, 52, 54–60, 62–65, 67–69, 73, and 76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 08/782,481. It is acknowledged that Applicants will file a terminal disclaimer when the claims are otherwise allowable.

Claims 42, 52, 54–60, 62–65, 67–69, 73, and 76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7 of

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U.S. Patent No. 6440419. It is acknowledged that Applicants will file a terminal disclaimer when the claims are otherwise allowable.

Claims 42, 52, 54–60, 62–65, 67–69, 73, and 76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims I–11 U. S.

5 Patent No. 7,022,309 (formerly copending Application No. 10/062467). It is acknowledged that Applicants will file a terminal disclaimer when the claims are otherwise allowable.

Claim Rejections - 35 USC § 112

Claims 73 and 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not
10 described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to or encompass a targeting molecule comprising a polypeptide wherein said polypeptide comprises a J chain or portion thereof encoded by nucleotides 1-213 of
15 SEQ ID NO: 8. It is unclear whether (1) on the one hand the polypeptide comprises either (i) a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 or (ii) a portion of a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8, or (2) on the other hand the polypeptide comprises either (iii) a J chain or (iv) a J chain portion encoded by nucleotides 1-213 of SEQ ID NO: 8.

Claims 73 and 76 also require that the targeting molecule does not contain at least one of
20 the domains selected from C_{H1}α, C_{H2}α, C_{H3}α, or C_L. Thus, it is clear that the claims do not require that the targeting molecule comprise any of C_{H1}α, C_{H2}α, C_{H3}α, or C_L, regardless of how one construes the J chain or portion thereof.

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The only working examples in the present specification (Example 3) show the targeting of various biological agents linked to "TM." What constitutes "TM" in these examples cannot be ascertained. The evidence cited by the examiner shows that although the presence of the J chain in IgA or IgM polymers is needed in order to obtain SC binding, the J chain by itself does not constitute an SC-binding site. Accordingly, a description of a J chain or a J chain portion that forms (a) and contains (b) is not a description of a targeting molecule that binds an epithelial basolateral factor and is not a description of a J chain portion that is characterized in having the ability to bind to an epithelial basolateral factor because the J chain by itself does not constitute an SC-binding site.

Furthermore, a description of a J chain or a J chain portion that forms (a) and contains (b) is not a description of a targeting molecule comprising a polypeptide that forms (a) and contains (b) wherein said polypeptide comprises a portion of a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 because there is no limit on the size of the portion. The portion is construed to encompass a single amino acid. Furthermore, there is no functional limitation associated with this minimal structural feature in claims 73 and 76.

Claims 73 and 76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a targeting molecule comprising a J chain and the C_{H2} and C_{H3} domains of IgA or IgM, does not reasonably provide enablement for a targeting molecule that comprises a polypeptide that contains (a), forms (b), wherein said polypeptide comprises a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO: 8, and does not contain any of CH1 α , CH2 α , CH3 α , and C_L. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

See how the examiner construes the claims, above.

5 Applicants argue that amending the claims to include the limitation that the targeting molecule comprises a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO: 8 overcomes this rejection. Applicants' arguments have been fully considered but they are not persuasive. Firstly, the claims do not require that the targeting molecule comprise any of C_H1 α , C_H2 α , C_H3 α , or C_L. Thus, only structural feature is a J chain or some portion thereof. However,
10 the J chain by itself does not constitute an SC-binding site. Secondly, there is no limit on the size of the portion and the portion is interpreted to encompass a single amino acid. Furthermore, there is no functional limitation associated with the minimal structural features in claims 73 and 76.

Claim Rejections - 35 USC § 102

15 Claims 73 and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Capra (U. S. Patent No. 6,063,905).

Applicants argue that Capra does not teach a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO: 8. Applicants' arguments have been fully considered but they are not persuasive. The claims are directed to or encompass a targeting molecule comprising a
20 polypeptide wherein said polypeptide comprises a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO: 8. It is unclear whether (1) on the one hand the polypeptide comprises either (i) a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 or (ii) a portion of

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a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8, or (2) on the other hand the polypeptide comprises either (iii) a J chain or (iv) a J chain portion encoded by nucleotides 1-213 of SEQ ID NO: 8. Capra's molecule obviously comprises (2)(iii) a J chain. Furthermore, Capra's molecule comprises (1)(ii) a portion of a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8, because there are no limits on the size of the portion and the portion is construed as a single amino acid.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 42, 52, 54-60, 62-65, 67-69, 73, and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to or encompass a targeting molecule comprising a polypeptide wherein said polypeptide comprises a J chain or portion thereof encoded by nucleotides 1-213 of SEQ ID NO: 8. It is unclear whether (1) on the one hand the polypeptide comprises either (i) a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 or (ii) a portion of a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8, or (2) on the other hand the polypeptide comprises either (iii) a J chain or (iv) a J chain portion encoded by nucleotides 1-213 of SEQ ID NO: 8. The metes and bounds are not clearly set forth.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex*

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parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 42, 52, 54-60, 63-65, 67-69, 73, and 76 recite the broad recitation "biological agent", and the claim also recites "antigen combining site" which is the narrower statement of the range/limitation. The claims are indefinite because "antigen combining site" typically refers to an antibody. However, the "biological agent" is not limited to an antibody. Thus, it is unclear how to construe the term "antigen combining site of at least one biological agent." The metes and bounds are not clearly set forth.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
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